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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/399,003	09/20/99	HOGREFE H	04121.0116-0

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EXAMINER	
HOUTTEMAN, S	
ART UNIT	**PAPER NUMBER**
1656	6

DATE MAILED: 12/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/399,003	Hogrefe et al.
Examiner	**Group Art Unit**
Scott Houtteman	1656

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____*three*_____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-95* _____ is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-95* _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-39, 45 and 46 of allowed Application No. 08/822,774. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of both applications read on generically defined "Polymerase Enhancing Factor" proteins. The difference in scope among these claims is merely in the claiming of various functional fragments of the whole protein. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use functional fragments of the holoprotein. The ordinary artisan would have reasonably expected these fragments to function because it is well known and a matter of common knowledge that some minor portions of an enzyme protein can be altered without any effect on enzyme activity.

3. Claims 1-95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-95 are indefinite in the recitation of "polymerase enhancing factor" (PEF). According to the definition of PEF:

> "'PEF' includes purified naturally occurring polymerase enhancing factors and wholly or partially synthetic copies or active analogs thereof."

Specification, page 5, line 31 to page 6, line 1. The scope of "analog" is unclear. It is not clear how far one can diverge from the specific "PEF" structure recited in the claims while still being considered a "PEF" analog. It is not clear if certain structures of the original "PEF" must be maintained in the "analog," or if no structural similarity is required in an "analog," only the original "PEF" activity. Cancellation of the "analog" portion of the definition is suggested.

B. Claim 28 is drawn to a protein with the following complex limitation. The protein is (1) encoded by DNA, (2) the DNA is capable of stringent hybridization to a recited sequence, the recited sequence is defined as encoding protein either (3a) having a 17-18 kD denatured molecular weight or (3b) having a sequence at or within about 20 amino acids from the amino terminal end comprising SEQ ID 69 or 11.

It is very difficult, if not impossible to determine what the scope of a protein defined through 3 divergent functional definitions, one of them, the hybridization definition, is unrelated to protein function. For a similar reason, defining the scope of the claims using different, unrelated schemes, claims 1-95 are also indefinite.

C. Claims 1-95 are indefinite in the recitation of "or analogs thereof," "sequences hybridizable thereto," "degenerate variants thereof" and "wholly or partially synthetic protein." Each of these limitations suggests that the claim is broader than the sequence or other specific structure recited in the claims. The question is how much broader? There is no way to determine

how far from the recited protein one can drift and still be "an analog" or a "degenerate variant" It is unclear whether the claims encompass merely truncated proteins, completely different proteins having the same activity, proteins having similar three dimensional structure or proteins encoded by DNA in which only the encoding DNA shares a characteristic.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling for the specific *Pyrococcus furiosus* protein isolated as set forth in the specification, defined either by it denatured molecular weight or by its unique DNA sequence. The specification, however, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are broadly drawn to a protein activity. The protein itself is variously described as a protein "or analogs thereof," "degenerate variants thereof" and "wholly or partially synthetic protein." The protein is also defined as encoded by DNA or "sequences hybridizable thereto." The claims recite the source of the protein as "bacterial, eukaryotic . . ." and thus broadly encompass both the animal and plant kingdoms.

The specification, in contrast, merely discloses a single example, the isolation of a UTPase protein from *Pyrococcus furiosus*. The specification offers no guidance on how one could isolate proteins from other species. There is no information on whether the sequence of this protein is conserved across evolutionary lines.

In view of the breadth of these claims, the small number of examples (one), the unpredictability of proteins and the lacking of guidance in the specification, it would require undue experimentation to enable a reasonable number of embodiments within the

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

6. Claims 1-95 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sorge et al., US Pat. 5,556,772; 9/1996, filed 2/1994 (Sorge).

Sorge discloses a compositions of matter, mixtures, kits, complexes and proteins isolated from *Pyrocossus furiosus*, that enhances polymerase activity by increasing fidelity. See, for example, Sorge col. 5 line 1 to col. 6, line 17.

Sorge differs from claims 1-20, 23, 28-39, 45, 59-66, 77-80, 85 and 87-92 in the recitation of protein "or analogs thereof," "degenerate variants thereof" and "wholly or partially synthetic protein," proteins defined as encoded by DNA or "sequences hybridizable thereto," specific molecular weights and SEQ ID NO:'s and an antibody defined as binding the protein. Nevertheless, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the composition in the various manner claimed.

These differences are mere variations on a theme. Given the Sorge disclosure of the references teaching the isolation of the *Pyrococcus furiosus* DNA polymerase (Sorge col. 6, line 15) the ordinary artisan would have been motivated to repeat this purification method. The resulting extract will implicitly contain the naturally occurring protein complexes.

With respect to the claimed nucleic acid sequences Sorge discloses the cloning and sequencing of the *Pyrococcus furiosus* DNA polymerase. The ordinary artisan would have been motivated in claiming the nucleic acid sequence of the gene product for the expected benefit of making the gene product easier to synthesis in large amounts and in pure form.

Also, while Sorge does not disclose the specific molecular weights or SEQ ID NO:s, it is noted that the claims are not limited to any specific molecular weights or SEQ ID NO:s in view of the broadening language such as: "or analogs thereof," "degenerate variants thereof," "wholly or partially synthetic protein" and proteins defined as encoded by DNA or "sequences hybridizable thereto."

Finally, the generation of an antibody from any protein is a matter of common knowledge. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention

was made to generate the antibody for the expected benefit of constructing an immunologic assay for the presence of the protein.

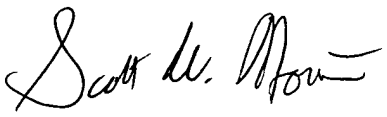
7. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
December 17, 2000



SCOTT W. HOUTTEMAN
PRIMARY EXAMINER